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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,719	11/10/2003	Steve Cote	14485.156US01	4984

23552 7590 04/06/2007

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EXAMINER	
KOHARSKI, CHRISTOPHER	
ART UNIT	PAPER NUMBER
3763	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/705,719	COTE ET AL.	
	Examiner	Art Unit	
	Christopher D. Koharski	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/18/07, 2/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 1/18/2007 in which claims 1,2 and 21 were amended and claims 9-20 were cancelled. Currently claims 1-8 and 21-24 are pending for examination.

Information Disclosure Statement

The information disclosure statements (IDS) that were submitted on 1/18/2007 and 2/12/2007are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 4-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunn et al. (2004/0158207). Hunn et al. discloses an infusion set device for cannula insertion.

Regarding claims 1 and 4-7, Hunn et al. discloses a method for introducing an infusion device comprising an infusion device (1) onto a needle (8) of an insertion device so the needle extends through the cannula (3) of the infusion device whereby the system is placed adjacent the skin of a patient ([0073-0076]) wherein the cannula is manually introduced into the subcutaneous layer of skin of the patient by pressing a button (24) triggering the needle to move relative to coupled sleeve (6) which hides the needle (8) prior to retraction or insertion and then after insertion the needle mechanism can be configured to be automatically withdrawn (Figures 9-13) ([0077-0078]). Additionally, an infusion device (2) includes a cannula (3) and method of coupling the system (Figures 1, 2 and 5) wherein positioning the assembly includes placing the set into a locked and unlocked state for fluid transfer ([0067-0068]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-3 are rejected under 35 U.S.C 103(a) as being unpatentable over Hunn et al. in view of Mogensen et al. (2003/0109829). Hunn et al. meets the claim limitations as described above except for the inclusion of a cap element and Applicants claimed associated steps.

However, Mogensen et al. teaches an injector device for placing a subcutaneous infusion set.

Regarding claims 2-3, Mogensen et al. teaches the step of providing a cap (94) to the insertion device and removing the cap prior to insertion into the of the system into the body (Figures 1-5) ([0028-0035]).

At the time of the invention, it would have been obvious to include the cap of Mogensen et al. to the system of Hunn et al. because the addition of cap element keep the system sterile and allows for needle stick protection. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Mogensen et al.

Claim Rejections - 35 USC § 103

Claim 8 is rejected under 35 U.S.C 103(a) as being unpatentable over Hunn et al. in view of Larsen et al. (6,736,797). Hunn et al. meets the claim limitations as described above except for the step of using a rotational locking mechanism of the infusion set.

However, Larsen et al. teaches a subcutaneous infusion set.

Regarding claim 8, Larsen et al. teaches reorienting the set rotationally relative to the site and moving the system from a locked to unlocked position (Figures 1 and 5, col 5 ln 1-53, col 8 34-49).

At the time of the invention, it would have been obvious to include the infusion set of Larsen et al. to the system of Hunn et al. because the addition of a rotational system allows for easy coupling and access to the infusion site and set. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Larsen et al.

Claim Rejections - 35 USC § 103

Claims 21-24 are rejected under 35 U.S.C 103(a) as being unpatentable over Mogensen et al. in view of Hunn et al.

Regarding claims 21-24, Mogensen et al. discloses a method for introducing an infusion set comprising uncapping the insertion device to place the insertion device in a

delivery state wherein the device is placed adjacent to the skin, with a tamper evident seal placed (42) on the insertion device (Figures 1-5, [0028-0035]).

Mogensen et al. meets the claim limitations as described above except for automatically retracting and having a locked and unlocked infusion state.

Hunn et al. discloses an infusion set device for cannula insertion.

Regarding claims 21-24, Hunn et al. discloses a method for introducing an infusion device comprising an infusion device (1) onto a needle (8) of an insertion device so the needle extends through the cannula (3) of the infusion device whereby the system is placed adjacent the skin of a patient ([0073-0076]) wherein the cannula is manually introduced into the subcutaneous layer of skin of the patient by pressing a button (24) triggering the needle to move relative to coupled sleeve (6) which hides the needle (8) prior to retraction or insertion and then after insertion the needle mechanism can be configured to be automatically withdrawn (Figures 9-13) ([0077-0078]). Additionally, an infusion device (2) includes a cannula (3) and method of coupling the system (Figures 1, 2 and 5) wherein positioning the assembly includes placing the set into a locked and unlocked state for fluid transfer ([0067-0068]).

At the time of the invention, it would have been obvious to include the automatic needle retraction and locking infusion set of Hunn et al. to the system of Mogensen et al. because the addition of an automatic needle retraction system and locking setup allows for ease of use and an increase in patient comfort. The references are analogous in the art and with the instant invention; therefore, a combination is proper.

Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hunn et al.

Response to Arguments

Applicant's arguments filed 1/18/2007 have been fully considered but they are not persuasive. Applicant's Representative asserts that Hunn et al. does not disclose a sleeve coupled to the insertion device and a insertion device system that allows for manual insertion and automatic retraction of the needle device. Examiner disagrees, the insertion device of Hunn et al. (depicted in Figure 9) shows a system in which a sleeve (located adjacent the needle (8), 6B) covers the needle prior to insertion and retraction, additionally, the needle insertion device is placed onto the skin and it manually triggers via button means (24), and the device can be configured to automatically withdraw ([0077-0078]) the needle after the button is pressed and the needle inserts the cannula into the patients body.

Suggested Allowable Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests addition of structural/functional limitations drawn to the automatic retraction mechanism (Figures 86-87).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 3/27/07

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